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EXAMINER

SOROUGH, ALI

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/522,527 | <b>Applicant(s)</b><br>WRIGHT ET AL. |  |
|                              | <b>Examiner</b><br>ALI SOROUGH       | <b>Art Unit</b><br>1616              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 28-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 28-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/052009</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/05/2009 has been entered.

### ***Status of the Claims***

No new amendments have been filed. Therefore, claims 1-26 and 28-39 are currently pending examination.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-4, 6-23, and 29-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Osman et al. (International Application Published Under the PCT, Published 12/07/2000) as evidenced by Barry et al. (Atmosphere, weather, and climate, Published 1976).

Osman et al. teaches a microfoam comprising a physiologically acceptable gas that is dispersible in the blood and an aqueous sclerosant liquid wherein the sclerosant is aqueous polidocanol, the concentration of polidoconal being from 0.5 to 4% vol/vol in the liquid. The microfoam is characterized in that it has a density of 0.11 to 0.14 g/ml and a half-life of at least 2 minutes, more preferably 2.5 minutes, and most preferably 3 minutes. The more preferable physiologically acceptable blood dispersible gas comprises 99% or more oxygen with the remainder being carbon dioxide, nitrogen, and trace gases in the proportion found in atmospheric air. (See claims 49, 51, 55, and 58 and page 9, paragraph 1 and 3). Osman et al. further teaches a device for producing a microfoam where the chamber is pressurized at 0.01 to 0.9 bar over atmospheric pressure and comprises pressurized source of physiologically acceptable gas and upon an activation mechanism the gas being contacted with aqueous sclerosant liquid wherein the microfoam passes through a passage of cross-sectional dimension 0.1 to 30 $\mu$ m, preferably 5 to 25 $\mu$ m, and more preferably 10 to 20 $\mu$ m. (See claims 19, 20, 21 and 30 and page 11, paragraph 1). The canister is made by the method comprising pre-purging with 100% oxygen for 1 minute, filling the canister with 15 ml of sclerosing agent, and pressurizing with oxygen of 1.7 bar over atmospheric pressure and maintained at this pressure through the use of the canister. (See page 24, example 2).

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Osman et al. further teaches a method of treating a patient in need of sclerotherapy of a blood vessel comprising administering a microfoam to the blood vessel. The canister is such that it contains sufficient gas and solution to form up to 500ml of microfoam, more preferably 1 to 200 ml and most preferably 10 to 60 ml of microfoam to treat at least one varicose human saphenous vein. (See claim 65 and page 19, paragraph 5). With regard to the instantly claimed amount of nitrogen gas being present, Osman et al. anticipates the instant concentration since it teaches that the remaining 1% of gas that is not oxygen should include nitrogen in the proportion found in air. Barry et al. teach that nitrogen is found to be 78.08% of the total composition of air. (See page 25, Table 1.1). Therefore, the amount of nitrogen in the gas composition of Osman et al. would be 0.78% which reads on the instant claims. Therefore, the instant claims are anticipated by the prior art.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.

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3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 5, 24, 25, 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osman et al. (International Application Published Under the PCT, Published 12/07/2000) as evidenced by Barry et al. (Atmosphere, weather, and climate, Published 1976).

### ***Applicant Claims***

Applicant claims foam comprising a sclerosing agent and gas phase of 0.0001 to 0.5% nitrogen gas and at least one physiologically acceptable gas; a canister comprising the components of the foam and method of making the canister. Applicant further claims a method treating a patient with an injection of the foam.

### ***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

The teachings of Osman et al. are discussed above.

### ***Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)***

Osman et al. teaches a gas phase comprising carbon dioxide, oxygen, and minor amount of nitrogen gas. However, Osman et al. does not anticipate a gas phase comprising 0.0001 to 0.5% nitrogen gas but does make such a gas phase obvious.

### ***Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)***

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It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have a gas phase comprising a mixture of carbon dioxide, oxygen, and 0.01 to 0.5% of nitrogen gas. One would have been motivated to use such a composition because Osman et al. teaches a gas phase comprising preferably 70 to 80% oxygen, 20 to 30% carbon dioxide, and a minor amount of nitrogen. It would therefore mean that the composition may comprise between 0 to 10% nitrogen which covers the instantly claimed concentration of 0.01 to 0.5% nitrogen. For the foregoing reasons the instantly claimed invention would have been obvious to one of ordinary skill in the art at the time of the instant invention.

2. Claims 37-39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osman et al. (International Application Published Under the PCT, Published 12/07/2000) as evidenced by Barry et al. (Atmosphere, weather, and climate, Published 1976) in view of Frullini et al. (Sclerosing Foam in the Treatment of Varicose Veins and Telangiectases: History and Analysis of Safety and Complications, Published 01/2002).

### ***Applicant Claims***

Applicant claims foam comprising a sclerosing agent and gas phase of 0.0001 to 0.8% nitrogen gas and at least one physiologically acceptable gas. Wherein the gas bubbles of the foam are no greater than 500µm and are primarily less than 280µm in diameter.

### ***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

The teachings of Osman et al. is disclosed above.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims  
(MPEP §2141.012)***

Osman et al. is silent as the size of the gas bubbles of the foam. This deficiency is cured by Frullini et al.

Frullini et al. teach, "The definition of a sclerosing foam (SF) is a mixture of gas and liquid sclerosing solution (detergent type) with tension-active properties. The gas must be well tolerated or physiologic and the bubble size less than 100 $\mu$ ." (See page 11, Column 1, Lines 5-8). Frullini et al. further teaches that there is "a higher rate of side effects" due to "the large size of the bubbles which easily spread along vessels." (See page 12, Column 1, Lines 28-30).

***Finding of Prima Facie Obviousness Rational and Motivation  
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the instant invention combine the teachings of Osman et al. with Frullini et al. Therefore, one of ordinary skill in the art at the time of the instant invention would through routine optimization arrive at the instant claimed bubble size diameter in light of the teachings of Frullini et al. One would have been motivated to do so in order to provide foam that has a minimal amount of side effects. For the foregoing reasons the instantly claimed invention would have been obvious to one of ordinary skill in the art at the time of the instant invention.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925.



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The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number For the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush  
Patent Examiner  
Art Unit: 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616